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Atty Dkt. No.: PALO-004  
USSN: 10/748,976REMARKS

In view of the following remarks, the Examiner is respectfully requested to withdraw the rejections and allow Claims 1-11 and 17-20; the only claims pending and under examination. In addition, the Examiner is respectfully requested to also allow Claims 12-14 and 21-31 which were previously withdrawn for being drawn to unelected species but depend from an allowable generic claim.

The Applicants thank the Examiner for the telephonic interview on November 17, 2006. The issue of whether Rezai in view of Verrier et al. render Claim 1 obvious was discussed. The Examiner agreed to consider the argument that Rezai in view of Verrier et al. do not render obvious Claim 1, and all claims depending from Claim 1, because Verrier et al. only disclose determining the sympathetic activity/parasympathetic activity ratio of an individual with a potentially fatal heart condition.

CLAIM REJECTIONS UNDER 35 USC § 103(A)

Claims 1, 4, 7, 9, 10, 17, 18 and 20 have been rejected under 35 U.S.C.103(a) as allegedly being obvious over Rezai (U.S. Patent Application No. 2005/0065574) in view of Verrier et al. (U.S. Patent No. 5,437,285). Applicants respectfully traverse this rejection.

According to the MPEP § 706.02 (j), to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

Claim 1 is directed to a method of treating a **female subject for a fertility condition** by determining the subject's sympathetic activity/parasympathetic activity ratio and modulating a portion of the subject's autonomic nervous system (ANS) to increase this ratio based on the determined sympathetic activity/parasympathetic activity ratio. Claims 4, 7, 9, 10, 17, 18 and 20 depend from Claim 1.

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Applicants respectfully assert that Rezai and Verrier et al., either alone or in combination, do not render the claims obvious, because there is no suggestion or motivation to combine Rezai and Verrier et al. with respect to a fertility condition. However, neither Rezai nor Verrier et al. disclose that the sympathetic activity/parasympathetic activity ratio has any connection with a fertility condition.

Rezai discloses affecting a "hypothalamic-related condition" by electrically or chemically stimulating the hypothalamus (see Abstract). Rezai discloses a list of over 55 conditions allegedly related to the hypothalamus. These conditions include an extremely diverse range of conditions including, infertility, baldness, narcolepsy, lethargy, dwarfism, and facial blushing (page 3, Table II). However, Rezai does not provide any further teaching or suggestion as to how the method is to be applied specifically to each condition.

In contrast, Verrier et al. disclose a method directed to individuals with potentially fatal heart conditions. In the "Abstract", Verrier et al. state that the method is "for predicting susceptibility to sudden cardiac death simultaneously assessing cardiac electrical stability and autonomic influence" (Abstract). In the "Summary of the Invention", Verrier et al. state that the method disclosed is for diagnosing "cardiac vulnerability to ventricular fibrillation" (and col. 6, lines 4-5). In the "Detailed Description of the Preferred Embodiment", Verrier et al. state the method is for "individuals at risk for sudden cardiac death" (col. 9, lines 50-51). In regards to sympathetic activity/parasympathetic activity ratio, Verrier et al. disclose that it is "indicative of sympathetic activity or vagal withdrawal" (col. 7, lines 28-29). For these reasons, it is very clear that Verrier et al. only disclose determining the sympathetic activity/parasympathetic activity ratio of an individual with a potentially fatal heart condition. Thus, based on the disclosure of Verrier et al. there is no suggestion or motivation to determine the sympathetic activity/parasympathetic activity ratio of an individual with a condition other than a potentially fatal heart condition.

Since Verrier et al. do not teach or suggest determining the sympathetic activity/parasympathetic activity ratio of a female subject with a fertility condition, there is no suggestion or motivation to combine Rezai and Verrier et al. with respect to a fertility condition. At best, if Rezai and Verrier et al. are combined, one skilled in the art

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might be motivated to stimulate the hypothalamus of a subject with a potentially fatal heart condition based on the feedback of the sympathetic activity/parasympathetic activity ratio of the subject.

For the reasons provided above, Rezai in view of Verrier et al. do not render Claims 1, 4, 7, 9, 10, 17, 18 and 20 obvious. Accordingly, Applicants respectfully request the Examiner to withdraw this rejection.

Claims 5, 6 and 11 have been rejected under 35 U.S.C.103(a) as allegedly being obvious over Rezai in view of Whitehurst et al. (U.S. Patent No. 6,832,114). Applicants respectfully traverse this rejection.

The three basic criteria to establish a *prima facie* case of obviousness, according to the MPEP § 706.02 (j), are described above.

Claims 5, 6 and 11 depend from Claim 1 which contains the element "**determining said sympathetic activity/parasympathetic activity ratio at least prior to said modulation and performing said modulation of said at least one portion of the ANS based on the determined sympathetic activity/parasympathetic activity ratio**".

As described above, Rezai discloses affecting a "hypothalamic-related condition" by electrically or chemically stimulating the hypothalamus (see Abstract), and discloses a list of over 55 conditions allegedly related to the hypothalamus (page 9, Table II). However, Rezai does not disclose determining the **sympathetic activity/parasympathetic activity ratio** of a subject and modulating the ANS of the subject based on the **determined sympathetic activity/parasympathetic activity ratio**.

The addition of Whitehurst et al. does not cure the deficiency of Rezai. Whitehurst et al. disclose modulating a patient's pancreatic endocrine secretion by electrical stimulation to treat diabetes. However, Whitehurst et al. do not disclose determining the **sympathetic activity/parasympathetic activity ratio** of a subject and modulating the ANS of the subject based on the **determined sympathetic activity/parasympathetic activity ratio**.

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Since neither Rezai nor Whitehurst et al. disclose this claim element, both references, either alone or combined, do not teach or suggest all the claim limitations of Claims 5, 6 and 11.

In addition, since Whitehurst et al. disclose treating diabetes but do not teach or suggest treating a female subject with a fertility condition, there is no suggestion or motivation to combine Rezai and Whitehurst et al.

Accordingly, as a *prima facie* case of obviousness is not established, the Applicants respectfully request the Examiner to withdraw this rejection.

Claim 8 has been rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Rezai in view of Mann et al. (U.S. Patent Application No. 2002/0055761). Applicants respectfully traverse this rejection.

The three basic criteria to establish a *prima facie* case of obviousness, according to the MPEP § 706.02 (j), are described above.

Claim 8 depends from Claim 1 which contains the element "determining said sympathetic activity/parasympathetic activity ratio at least prior to said modulation and performing said modulation of said at least one portion of the ANS based on the determined sympathetic activity/parasympathetic activity ratio".

For the reasons described above, Rezai does not disclose determining the sympathetic activity/parasympathetic activity ratio of a subject and modulating the ANS of the subject based on the determined sympathetic activity/parasympathetic activity ratio.

The addition of Mann et al. does not cure the deficiency of Rezai. Mann et al. disclose using electrical stimulation of a nerve to reduce or eliminate a bladder problem, but also do not disclose determining the sympathetic activity/parasympathetic activity ratio of a subject and modulating the ANS of the subject based on the determined sympathetic activity/parasympathetic activity ratio.

Since neither Rezai nor Mann et al. disclose this claim element, both references, either alone or combined, do not teach or suggest all the claim limitations of Claim 8.

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In addition, since Mann et al. disclose treating a bladder problem but do not teach or suggest treating a female subject with a fertility condition, there is no suggestion or motivation to combine Rezai and Mann et al.

Accordingly, as a *prima facie* case of obviousness is not established, the Applicants respectfully request the Examiner to withdraw this rejection.

Claim 19 has been rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Rezai in view of Khan et al. (U.S. Patent Application No. 2002/0064501). Applicants respectfully traverse this rejection.

The three basic criteria to establish a *prima facie* case of obviousness, according to the MPEP § 706.02 (j), are described above.

Claim 19 depends from Claim 1 which contains the element "**determining said sympathetic activity/parasympathetic activity ratio at least prior to said modulation and performing said modulation of said at least one portion of the ANS based on the determined sympathetic activity/parasympathetic activity ratio**".

For the reasons described above, Rezai does not disclose determining the **sympathetic activity/parasympathetic activity ratio** of a subject and modulating the ANS of the subject based on the determined **sympathetic activity/parasympathetic activity ratio**.

The addition of Khan et al. does not cure the deficiency of Rezai. Khan et al. disclose using an immunoregulator to treat an immune-mediated disorder, including "chronic inflammatory disease, such as diabetes type I or II, rheumatic disease, Sjogrens syndrome, multiple sclerosis, transplantation-related immune responses such as graft-versus-host-disease, post-transfusion thrombocytopenia, chronic transplant rejection, pre-eclampsia, atherosclerosis, asthma, allergy and chronic auto-immune disease, and acute inflammatory disease" (paragraph [0028]). However, Khan et al. do not disclose determining the **sympathetic activity/parasympathetic activity ratio** of a subject and modulating the ANS of the subject based on the determined **sympathetic activity/parasympathetic activity ratio**.

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Since neither Rezai nor Khan et al. disclose this claim element, both references, either alone or combined, do not teach or suggest all the claim limitations of Claim 19.

In addition, since Khan et al. disclose treating an immune mediated disorder but do not teach or suggest treating a female subject with a fertility condition, there is no suggestion or motivation to combine Rezai and Khan et al.

Accordingly, as a *prima facie* case of obviousness is not established, the Applicants respectfully request the Examiner to withdraw this rejection.

**CLAIM REJECTIONS UNDER 35 USC § 102(e) OR, IN THE ALTERNATIVE, UNDER 35 USC § 103(A)**

Claims 2 and 3 have been rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Rezai or, in the alternative, under 35 U.S.C. § 103(a) as allegedly being obvious over Rezai in view of Bothe Loncar et al. (U.S. Patent Application No. 2002/0188336). Applicants respectfully traverse this rejection.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).<sup>90</sup>

Claims 2 and 3 depend from Claim 1 which contains the element "**determining said sympathetic activity/parasympathetic activity ratio at least prior to said modulation and performing said modulation of said at least one portion of the ANS based on the determined sympathetic activity/parasympathetic activity ratio**".

For the reasons described above, Rezai does not disclose determining the **sympathetic activity/parasympathetic activity ratio** of a subject and modulating the ANS of the subject based on the determined **sympathetic activity/parasympathetic activity ratio**.

Since Rezai does not disclose all the claim elements of Claims 2 and 3, Rezai does not anticipate Claims 2 and 3. Accordingly, Applicants respectfully request the Examiner to withdraw this rejection based on anticipation.

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The three basic criteria to establish a *prima facie* case of obviousness, according to the MPEP § 706.02 (j), are described above.

The addition of Bothe Loncar et al. do not cure the deficiency of Rezai. Bothe Loncar et al. disclose enhancing and regularizing autonomic nervous and endocrine function by stimulating specific discrete skin areas with copper and aluminum plates. However this reference does not disclose determining the **sympathetic activity/parasympathetic activity ratio** of a subject and modulating the ANS of the subject based on the determined **sympathetic activity/parasympathetic activity ratio**.

Since neither Rezai nor Bothe Loncar et al. disclose this claim element, both references, either alone or combined, do not teach or suggest all the claim limitations of Claims 2 and 3. Accordingly, as a *prima facie* case of obviousness is not established, the Applicants respectfully request the Examiner to withdraw this rejection.

**CLAIMS PREVIOUSLY DRAWN TO AN UNELECTED SPECIES**

Claims 12-14 and 21-31 were previously withdrawn for being drawn to unelected species. As these claims depend from an allowable generic claim, Applicants respectfully request the Examiner to allow Claims 12-14 and 21-31.

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CONCLUSION

The Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number PALO-004.

Respectfully submitted,  
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